In The Specification:

At page 7, line 3, please insert the following:

Figure 31 is a plan view of a delivery catheter or cannula that may be used for accessing the pericardial space through right ventricular apex.

Figure 32 is an exploded, cut-away view of the distal end of the catheter of Figure 31 after it has been fixed at an endocardial site.

At page 18, line 14, please insert the following paragraphs:

Figures 31 and 32 illustrate a delivery system that may be used for placing an elongated medical device in the pericardial space by passing the medical device through a pericardial access created through the myocardium of the heart wall of a heart chamber, particularly a pericardial access through the right ventricular apex. Implantable medical devices may be more easily positioned over the area or site of the left ventricle by accessing the pericardial space via the pericardial access through the right ventricular apex, thereby eliminating the need for a thorocotomy or other surgical access through the thorax. Such implantable medical devices include fluid delivery catheters for drug or diagnostic fluid delivery or electrical medical leads, e.g., pacing and/or cardioversion defibrillation leads and electrophysiological mapping and/or ablation catheters. Defibrillation thresholds can be significantly reduced when a defibrillation electrode of an elongated defibrillation lead is extended through the pericardial access and placed over the left ventricular free wall. Pacing of left heart chambers can be advantageously accomplished by advancing pacing leads through the pericardial access and locating

pace/sense electrodes at selected sites of the left ventricular or atrial epicardium.

Figure 31 is a plan view of an elongated tubular delivery device 902, e.g. a delivery catheter or cannula, which may be used in the formation of the pericardial access for accessing the pericardial space and an obdurator or leader 906 that is used during advancement of the tubular delivery device 902 transvenously into a heart chamber from a skin incision. Preferably, elongated tubular delivery device 902 is a catheter provided with an elongated tubular catheter body 910 that is provided with a fitting 920 at its proximal end, which may take the form of a Luer lock fitting. Catheter body 910 is preferably formed from a biocompatible polymer, such as polyurethane, a fluoropolymer, or silicone, and is preferably reinforced by an embedded braiding. Embedded braiding is preferably stainless steel, or a high strength polymer fiber such as polyester or nylon. Braided tubular bodies are known in the art, for example, as described in U.S. Pat. No. 5,713,867 issued to Morris, incorporated herein by reference in its entirety. A distal section 912 of the catheter body 910 is provided with greater flexibility than the remainder of the catheter body 910. Greater flexibility of the distal section 912 is provided to reduce the end loading force imposed by the tip of the catheter 902 when it is placed against the endocardium in order to minimize any injury or damage to the endocardial tissue. Distal section 912 may be formed from a lower durometer material than the remainder of catheter body 910.

A fixation member 904 extends from the distal end of the catheter 902. Fixation member 904 is shown as a fixation helix that may correspond generally to fixation member 746 shown in Figure 28. Fixation member 904 is used to fix the catheter 902 in position

against the endocardium and may additionally function as an electrode coupled to a conductor as described above and shown in Figure 28. Fixation member 904 may alternatively be provided as a barb, suction device, adhesive, or other appropriate fixation mechanism.

A leader 906 is shown exiting the distal end of fixation member 904 with its proximal end 918 entering the proximal end of fitting 920. Leader 906 acts to lead catheter 902 as it is advanced through a venous pathway into the right ventricle. Leader 906 prevents helical fixation member 904 from piercing or snagging on venous or cardiac structures along the way, thereby preventing fixation member 904 from causing unintentional tissue damage as catheter 902 is advanced. Leader 906 preferably takes the form of a steerable diagnostic catheter that allows electrophysiological measurements to be made to confirm placement of the catheter at a desired endocardial site. In an alternative embodiment, leader 906 may take the form of a thin-walled, pliant, polymeric, tubular sheath that extends from the distal end of catheter 902 over the outer diameter of fixation member 904. As fixation member 904 is advanced into the myocardium, the pliant polymeric sheath would be pushed back toward the distal end of catheter 902, allowing unhindered advancement of member 904.

Figure 32 is an exploded, cut-away view of the distal end of catheter 902 after it has been fixed at an endocardial site using fixation member 904. Fixation member 904 is advanced or screwed into the myocardial wall 100 by rotating the catheter body 910 at its proximal end. The embedded braiding in catheter body 910 provides torsional strengthening that transfers torque applied at the proximal end of catheter 902 to the distal fixation member 904.

In Figure 32, leader 906 has been removed from the lumen of catheter 902 and replaced with a pericardial access device that includes dilator 908 and an epicardial access device or puncturing device 914. Puncturing device 914 may take the form of a stylet or guidewire having a beveled or sharpened tip in order to puncture through the myocardium of the heart wall and extend into the pericardial space. A puncturing device may alternatively be provided as a needle or coring device, or any device suitable for piercing through the myocardium. Puncturing device 914 is passed through the lumen of dilator 908. Dilator 908 is sized such that its outer diameter fits within the inner diameter of catheter 902 and so that it may be easily advanced or withdrawn through catheter 902. The inner diameter of dilator 908 is sized such that puncturing device 914 may easily pass through the lumen of dilator 908. The wall thickness at the distal end 920 of dilator 908 is preferably reduced such that dilator 908 possesses a small profile at its distal end.

In use, dilator 908 and puncturing device 914 are advanced to the endocardial surface after fixation catheter 902 is positioned at a desired location. Dilator 908 provides stiffening support to puncturing device 914 so that puncturing device 914 may be advanced forward to pierce through the myocardial wall 100, and disposes the puncturing device 914 substantially in axial alignment with the axis of the catheter 902. In Figure 32, puncturing device 914 is shown partially advanced through the myocardial wall 100. Once through the myocardial wall 100, the puncturing device 914, no longer being constrained by dilator 908, lacks the stiffness to pierce through the relatively tougher pericardium. Dilator 908 may then be advanced through the myocardium into the pericardial space over puncturing device 914. The tip of dilator 908 may be

tapered or beveled to ease the process of advancing dilator 908 through the myocardium. The small profile at the distal end 920 of dilator 908 also eases the process of advancing dilator 908 through the myocardium, reducing the size of the myocardial puncture.

With the catheter 902 still fixed over the myocardial puncture, various medical devices may be introduced into the pericardial space through the created pericardial access. The medical devices can be advanced from the skin incision through the lumen of the dilator 908 or through the catheter lumen if the dilator 908 and puncturing device 914 are removed or over the puncturing device 914 left extending through the pericardial access after withdrawal of the dilator 908. For example, an over-the-wire pacing, sensing, or defibrillation lead may be advanced over puncturing device 914, after removing dilator 908. Fluids or other medical devices as described above may be delivered through dilator 908. A diagnostic catheter may be inserted to perform electrophysiological mapping of the left ventricular free wall so that an optimal location for a left ventricular lead may be determined.

In each of these cases and in others, an elongated medical device adapted to be advanced over a wire can be inserted through the delivery device lumen and through the pericardial access over the puncturing device 914 after removal of the dilator 908. In certain cases, it may be possible to also detach and withdraw the catheter 902, so the elongated medical device can be advanced over the puncturing device 914 and through the pericardial access into the pericardial space.

Elongated medical devices having sufficient pushability can also be simply advanced through the delivery device lumen and the pericardial access aligned with it after removal of the puncturing device 914 and the dilator 908 from the delivery device lumen.

The catheter delivery system shown in Figures 31 and 32 has been described with regard to accessing the pericardial space via the right ventricle. It is further contemplated that the system described above may be used to access the pericardial space via the left ventricle, for example by introducing the catheter through the femoral artery and guiding the catheter into the left ventricle. The delivery system shown in Figures 31 and 32 is also contemplated for use in accessing the interior of the left heart chambers via a septal puncture. Catheter 902 may be fixed on the septal wall of the right ventricle or right atrium and puncturing device 914 and dilator 908 may be advanced through the septum into the left chambers of the heart.